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1632

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/016,993
Filing Date	December 13, 2001
First Named Inventor	WILES
Art Unit	1632
Examiner Name	Michael C. Wilson
Attorney Docket Number	R-948

Total Number of Pages in This Submission

ENCLOSURES (*Check all that apply*)

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☑ Amendment/Reply
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
- ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance Communication to a Technology Center (TC)
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please Identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Kelly L. Quast, Reg. No. 52,141
Signature	Kelly L Quast
Date	August 13, 2003

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: August 13, 2003

Typed or printed	Don Mixon		
Signature	Don Mixon	Date	August 13, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	**Michael V. WILES *et al.***	Group Art Unit:	**1632**
Serial No.:	**10/016,993**	Examiner:	**Wilson, Michael C.**
Filed:	**December 13, 2001**	Customer No.	**26619**
Title:	**Transgenic Mice Containing Alpha-Endosulfine Gene Disruptions**	Docket/Order No.	**R-948**
		Date:	**August 13, 2003**

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Mail Stop Non-Fee Amendments
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed July 16, 2003 concerning the Examiner's restriction to the claims in connection with the above-referenced application, Applicants elect without traverse Group II (claims 5-8, 10 and 14-18), drawn to a cell having a disruption in an alpha-endosulfine gene, and a transgenic animal having a disruption in an alpha-endosulfine gene.

Respectfully submitted,

Date: 8/13/03

Kelly L. Quast, Reg. No. 52,141
Deltagen, Inc.
700 Bay Road
Redwood City, CA 94063
(650) 569-5100

Enclosures

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence and its listed enclosures is being deposited with the United States Postal Service as First Class Mail, postage paid, in an envelope addressed to: Commissioner for Patents, Alexandria, VA, Mail Stop Non- Fee Amendment/OIPE on **August 13, 2003**.

Name: **Don Mixon**

Signed: Donald Mixon Date: 8/13/03

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,993	12/13/2001	Michael V. Wiles	R-948	4978

7590 07/16/2003

DELTAGEN, INC.
740 Bay Road
Redwood City, CA 94063

EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,993	WILES ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-20 are pending and under consideration.

The computer readable format of the sequence listing filed had errors, but was entered by STIC. The disk had non-ASCII "garbage" at the beginning/end of files that were deleted by STIC.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a construct having a first and second polynucleotide sequence homologous to an alpha-endosulfine gene and a selectable marker, classified in class 435, subclass 320.1.

II. Claims 5-8, 10 and 14-18, drawn to a cell having a disruption in an alpha-endosulfine gene, classified in class 435, subclass 325, and transgenic animals having a disruption in an alpha-endosulfine gene, classified in class 800, subclass 8,

III. Claim 11, drawn to a method of identifying a compound using a transgenic animal having a disruption in an alpha-endosulfine gene, classified in class 800, subclass 3.

IV. Claim 12, drawn to a method identifying a compound using a cell having a disruption in an alpha-endosulfine gene, classified in various classes and subclasses.

V. Claims 13, drawn to agents that modulate expression or function of alpha-endosulfine protein, classified in numerous classes and subclasses.

VI. Claim 19, drawn to a method of identifying compounds using alpha-endosulfine protein, classified in class 530, subclass 350.

VII. Claim 20, drawn to a method of identifying compounds using cells transfected with DNA encoding alpha-endosulfine protein or encoding a reporter gene operably linked to an alpha-endosulfine promoter, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not used together. The targeting construct does not have a disruption in the alpha-endosulfine gene while the cells and animals of Invention II require a disruption in the alpha-endosulfine gene.

Inventions I and III or IV are patentably distinct because the construct can be used to encode alpha-endosulfine protein while the claims of Invention III or IV must have a disruption in the alpha-endosulfine gene. DNA encoding alpha-endosulfine has a different structure and function than cells or transgenics having DNA with a disruption in the alpha-endosulfine gene. The burden required to search DNA encoding alpha-endosulfine and disrupting an alpha-endosulfine gene together would be undue.

Inventions I and V are unrelated. The protocols and reagents required for targeting constructs are materially distinct and separate from those required for agents that modulate expression or function of an alpha-endosulfine protein. The agents do not require the targeting construct and vice versa.

Inventions I and VI or VII are patentably distinct because the construct can be used to disrupt the alpha-endosulfine gene while the methods of Inventions VI or VII requires the alpha-endosulfine protein. The protocols and reagents required for targeting constructs are materially distinct and separate from those required for protein assays. The targeting construct does not require the methods and the methods do not require the targeting construct.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method can be performed using cells or transgenics. The burden required to search an in vitro method with an in vivo method would be undue.

Inventions II and IV are related as product (cells) and process of use (method of using cells in any assay). In the instant case the method can be performed using cells or transgenics. The burden required to search an in vitro method with an in vivo method would be undue.

Inventions II and V are patentably distinct because, for example, transgenics are used as in vivo models while the agents are used to treat disease. The protocols and reagents required for cells or transgenics having a disruption of an alpha-endosulfine gene are materially distinct and separate from those required for agents that modulate expression or function of an alpha-endosulfine protein. The cells/transgenics do not require the agents and vice versa.

Inventions II and VI or VII are patentably distinct because the cells or transgenics of Group II require a disruption of alpha-endosulfine proteins while the methods of Groups VI and VII require using the alpha-endosulfine protein. The protocols and reagents required for cells/transgenic having a disruption in a protein are materially distinct and separate from those required for using the protein to identify compounds. The cells/transgenics do not require the protein used in the methods of Group VI and VII, and the methods of Groups VI and VII do not require the cells/transgenics.

Inventions III and IV are patentably distinct because the method of Group III requires a transgenic while the method of Group IV requires cells. The protocols and reagents required for testing compounds *in vivo* are materially distinct and separate than those required to test compounds *in vitro.* The method of Group III does not require the method of Group IV and vice versa. The burden required to search an in vitro method with an in vivo method would be undue.

Inventions III and V are patentably distinct because the method is used to identify compounds while the agents are used to treat disease. The protocols and reagents required for using transgenics having a disruption of an alpha-endosulfine gene are

materially distinct and separate from those required for agents that modulate expression or function of alpha-endosulfine protein. The method does not require the agents and vice versa.

Inventions III and VI or VII are patentably distinct because the transgenics of Group III require a disruption of alpha-endosulfine proteins while the methods of Group VI and VII require using the alpha-endosulfine protein. The protocols and reagents required for using a transgenic having a disruption in a protein are materially distinct and separate from those required for using the protein to identify compounds. The methods do not require the protein and the methods do not require using transgenics.

Inventions IV and V are patentably distinct because the method is used to identify compounds while the agents are used to treat disease. The protocols and reagents required for using cells having a disruption of an alpha-endosulfine gene are materially distinct and separate from those required for agents that modify expression or function of alpha-endosulfine protein. The method does not require the agents and vice versa.

Inventions IV and VI or VII are patentably distinct because the cells used in the method of Group IV require a disruption of alpha-endosulfine proteins while the methods of Group VI requires the alpha-endosulfine protein and the method of Group VII requires the cells express an alpha-endosulfine protein. The protocols and reagents required for using cells having a disruption in a protein are materially distinct and separate from those required for using the protein or cells expressing the protein to

identify compounds. The method of Group IV does not require the methods of Group VI or VII and the methods of Group VI or VII do not require the method of Group IV.

Inventions V and VI or VII are patentably distinct because the agent is used to modify the expression or function of alpha-endosulfine protein while the methods are used to identify compounds and requires the alpha-endosulfine protein. The protocols and reagents required for agents are materially distinct and separate from those required for using the protein to identify compounds. The agent does not require the method and the method does not require the agent.

Inventions VI and VII are patentably distinct because the method of Group VI requires protein while the method of Group VII requires transfected cells. The protocols and reagents for making and using protein and transfected cells are materially distinct and separate. The method of Group VI does not require the method of Group VII and the method of Group VII does not require the method of Group VI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I-IX is separate, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

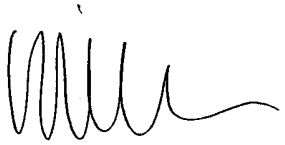
Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER